GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@ge.com

Certified Mail Return Receipt Requested

Important Electronic Product Radiation Warning

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

June 12, 2007

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**OEC ® 9900 Elite** **OEC ® 9800** **OEC ® 8800** **OEC ® 6800** **OEC ® 2800**

Our records indicate that your facility currently has one or more of the products listed above.

GE Healthcare has identified an issue affecting these products as described below. This communication is intended to provide clarification on the prior communication dated April 2, 2007.

Failure to display Air Kerma and Cumulative Air Kerma:

A configuration issue has been discovered that results in the failure of the system to display the International Standard quantity, air kerma, to describe the radiation output. The usage of Air Kerma to replace entrance exposure, and the display of Air Kerma Rate and Cumulative Air Kerma are required on systems manufactured after June 10, 2006 by 21 CFR 1020.32(k). In GE OEC systems, AKR (air kerma rate) is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK (cumulative air kerma) is calculated from the same, but accumulated over the duration of the procedure.

These systems, as shipped, did not meet the requirement of 21 CFR 1020.32(k), in that the systems were not configured to display Air Kerma Rate and Cumulative Air Kerma at the operators working position on individually distinguishable displays.

This issue does not impact the safety of operation of your system, however does result in non-compliance to 21CFR 1020.32 (k).

Your GEHC Surgery service representative will be contacting you in the near future to arrange for an inspection and to modify your system configuration if necessary to assure compliance with the requirements of 21 CFR 1020.32(k) at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@med.ge.com

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 21 2007

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **OEC UroView 2800, OEC 9800 Plus Digital, OEC MiniView 6800, OEC FlexiView 8800 Mobile C-Arm**

Our records indicate that your facility has one or more of the following GE Healthcare OEC (GEHC OEC) devices that has received a replacement hard disk drive:

- OEC UroView 2800
- OEC 9800 Plus Digital
- OEC MiniView 6800
- OEC FlexiView 8800 Mobile C-Arm

GEHC OEC has discovered an issue with the hard disk drives that were installed on the above listed products during service calls. The manufacture dates of the affected hard disk drives are between October 15, 2004 and December 8, 2004

This issue could potentially result in the system failing to store images when the hard disk drive capacity exceeds 170 images instead of the expected 400 images. Systems may also fail to boot or lose patient data as this image capacity is approached.

DOC0287403

Your GEHC OEC Field Service Engineer will be contacting your facility to arrange to have a replacement hard disk drive installed on your system.

Until a GEHC OEC Field Service Engineer has replaced the hard disk drive users should ensure that images on the hard disk drive are stored via an alternate permanent media (film, long term storage) as the hard disk drive approaches the 170 image capacity.

GEHC OEC is actively working to replace the affected hard disk drives in a timely manner. GEHC OEC will, without charge, remedy this issue.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

IMPORTANT RADIATION SAFETY NOTICE – 9900 PRODUCT

GE Healthcare
OEC Medical Systems, Inc.
384 Wright Bros. Drive
Salt Lake City, Utah 84116
Phone: 801-328-9300
Fax: 801-328-4300

Date: August 14, 2006

To: Facility Administrator and Radiation Safety Officer

GE Healthcare recently learned that your 9900 C-Arm might exceed the 20 R/minute limit required by the Code of Federal Regulations when in High Level Fluoro (HLF) Pulsed Mode and may pose a serious radiation hazard to both the patient and staff. This could occur if the Default Pulse Rate is set to 30 PPS on the 9900 C-Arm. Only a Field Service or Biomedical Engineer can manually change this value using RUS (Remote Utility Suite Software) or RUT (Remote Utility Tool). The user cannot select it.

At the time of this letter we have already initiated a mandatory system software upgrade for the 9900 product that is required for all systems manufactured prior to 5/19/06. This upgrade requires the new RUS software with the fix to prevent the Default Pulse Rate being set to 30 PPS. If your system has been upgraded the 30 PPS option cannot be selected. You can determine your software version by pressing the HELP Screen and looking at the WS NODE that should display 6.15.1 or 6.15.3. If your system has not been upgraded, please contact your GE service team at 800-874-7378 to schedule the upgrade.

In the meantime, you can do the following steps to determine if this issue affects your system:

1. Power the system up.
2. Press the PULSE button on the C-Arm
3. If 30 PPS is displayed in the status bar on the right workstation monitor, the Default Pulse Rate is set to 30 PPS.
4. If 30 PPS is displayed **PLEASE IMMEDIATELY DISCONTINUE any use of the High Level Fluoro Pulsed mode** and contact your service team at 800-874-7378 for a priority service visit to correct this problem.

If 30 PPS is NOT displayed, your system complies with the federal regulation and no further action is required

GE OEC will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan approved by the Secretary of Health and Human Services.

For Further information, please contact your service team at 800-874-7378.

Sincerely yours,

Kenneth F. Miles, Ph.D.

Kenneth F. Miles, PhD.
Vice President Regulatory Affairs and Quality Assurance
GE OEC Medical Systems, Inc.

GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@med.ge.com

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

January 12, 2007

To: **Director Surgery/Urology**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: OEC® UroView 2800 and OEC® UroView 2800 with Dual Monitor Option

Our records indicate that your facility has one or more **OEC® UroView 2800 and/or OEC® UroView 2800 with Dual Monitor Option**

GE Healthcare has identified two (2) potential safety issues that may occur with the **OEC® UroView 2800** product based upon feedback from some customers. The details of these issues, as well as the associated interim solutions, are outlined below.

1. Dual Monitor Safety Risk:

Affected Products: OEC® UroView 2800 Dual Monitor Configuration

There have been instances in which the dual monitor on a Uroview 2800 became disconnected from the assembly arm. **The dual monitor assembly arm on the Uroview 2800 could pose a safety risk to patients, users, or other personnel should the monitors become disconnected.**

A small hardware component on your Uroview 2800 needs to be inspected and possibly modified to correct this potential safety risk. Your GEHC-OEC Field Service Engineer will be contacting your facility to inspect your Uroview 2800 to see if it is impacted by this potential risk. If your system is

affected, your GEHC-OEC Field Service Engineer will be able to make the needed modification to your Uroview 2800 at that time.

Interim Solution:

Until a GE OEC Field Service Engineer has inspected your Uroview 2800 with the Dual Monitor Option, please cease using your Uroview 2800 for procedures where the use of the dual monitors is required. In addition to reduce the potential of the monitors falling and causing injury:

- **Follow the instructions below for the positioning of the monitors and placement of the enclosed warning tag**
- **Do not move the monitors from this position until your Uroview 2800 has been inspected and/or repaired.**

INSTRUCTIONS FOR MONITOR PLACEMENT

- Position the dual monitors so that they rest on top of the tower as shown in Figure #1 (Please be advised that this should be done carefully or you could scratch the surface of the generator housing.)
- Attach the WARNING Tag (Example of Tag in Figure #2) to the left or right dual monitor handles as shown in Figure #3 with the supplied Cable Tie. (Please note that the tag should be placed in such a manner that the WARNING Tag is clearly visible to any user)

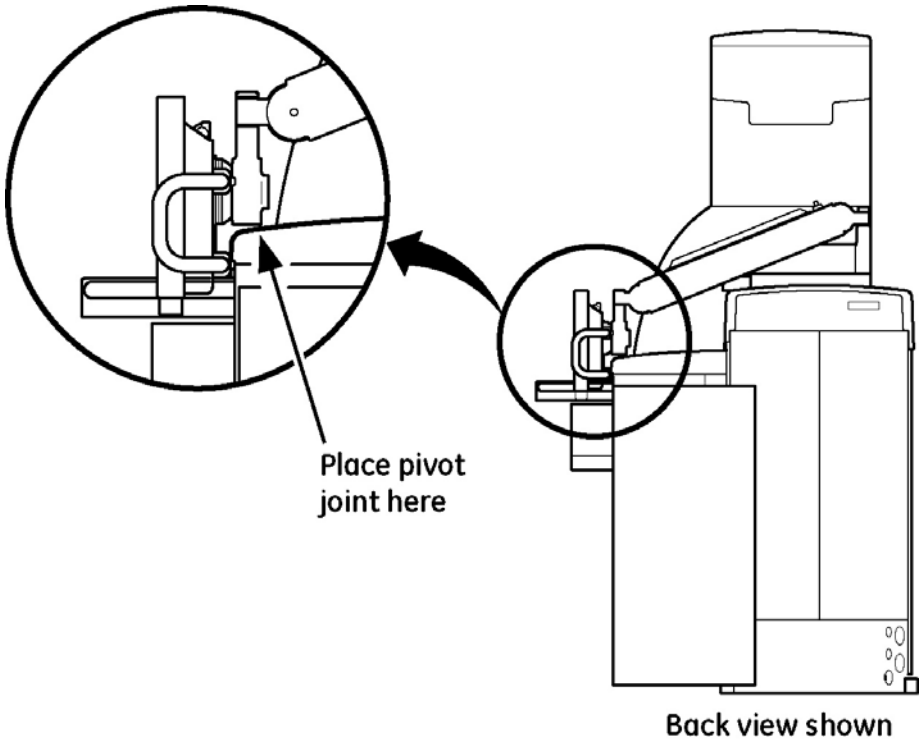


Figure #1 – Mount Monitors as shown in Back View of System

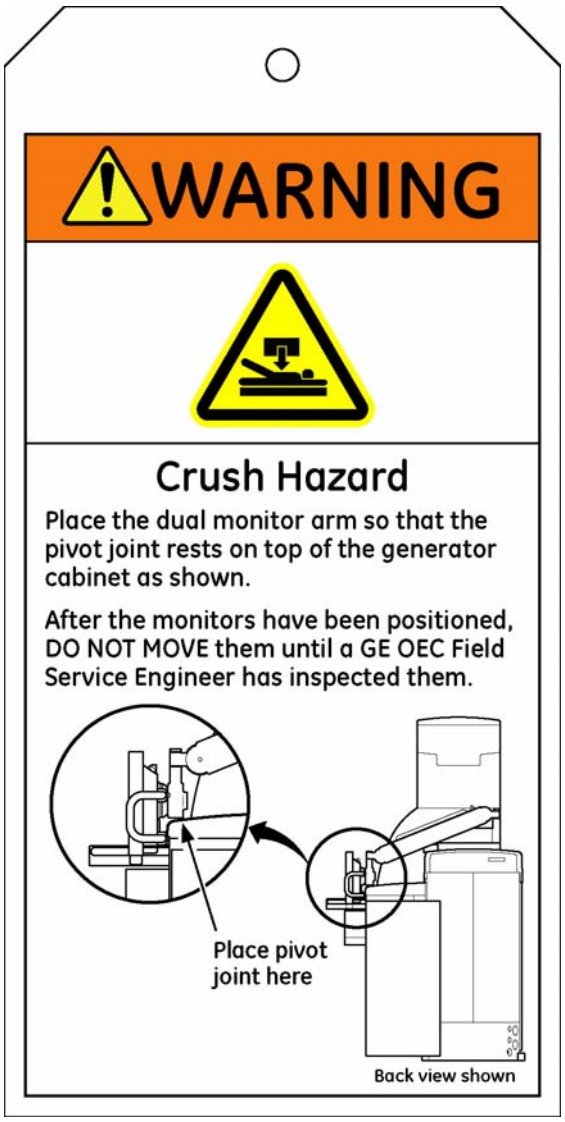

WARNING
Crush Hazard
Place the dual monitor arm so that the pivot joint rests on top of the generator cabinet as shown.
After the monitors have been positioned, DO NOT MOVE them until a GE OEC Field Service Engineer has inspected them.
Place pivot joint here
Back view shown

Figure #2 – Example of WARNING Tag – Apply to 2800 Dual Monitor Handle

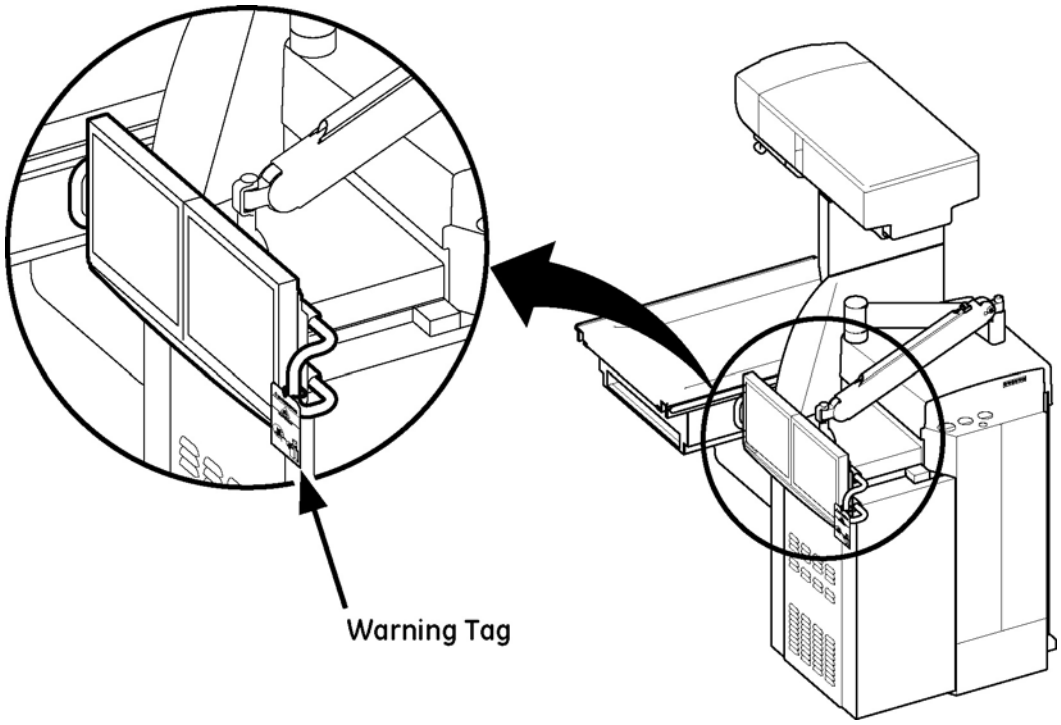


Figure #3 – WARNING Tag Position on 2800 System

2. 2800 3 Phase Power Distribution Box Shock Hazard:

Affected Products: OEC® UroView 2800

The 2800 3 Phase Power Box has been found to be not in compliance with the specifications. The following issues have been identified that can present a potential electrical safety hazard:

- Interlock mechanism on some boxes prevents the user from energizing the panel without first disengaging the mechanism .The effected locking mechanism is located inside the door and should allow the user to engage the power to the Power Box with the door closed, this does not always function as designed and results in the user having to push on the door to be able to engage the power.
- External latch and interlock mechanism on some box doors have been found to be inadequate and could allow the door to open with power energized.
- User can engage power with the box door slightly open.

The box door should always be closed completely and the external latch engaged before energizing the unit.

2800 3 Phase Power Box

Interim Solution:

Until a solution has been identified and installed at your facility, users are cautioned to **ensure that the access door to the 3 Phase Power Box is completely closed when the unit is powered on**.
Failure to do so can present a shock hazard to the user.

GEHC OEC is actively working on solutions that will permanently resolve both of these issues. When solutions become available, GEHC OEC will contact you and without charge, remedy these issues.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours a day, 7 days a week.

Thank you,

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@med.ge.com

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

November 8, 2006

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, and OEC® Miniview 6800**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- FlexiView 8800 Mobile C-Arm
- OEC® Miniview 6800
- OEC® UroView 2800
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare has identified several intermittent potential safety issues that may occur with these products based upon feedback from some customers. The details and symptoms of these issues, as well as the associated interim or permanent solutions, are outlined below.

1. Navigation Tracking Inaccuracy:

Affected Products: OEC® FluoroTrak 9800 Plus

An issue has been discovered with the OEC® FluoroTrak 9800 Plus that could result in an incorrect position of instrumentation versus the displayed reference image. **This issue could result in an injury to the patient due to incorrect anatomical location of an instrument during a procedure.**

Permanent Solution:

GE OEC is currently investigating corrective solutions. When a corrective solution has been identified the GE OEC service team will contact your facility and arrange implementation of the corrective action.

Users are advised to stop using the system WITH NAVIGATION until this replacement has been successfully completed. OEC® FluoroTrak 9800 Plus system may be used as a standard C-Arm providing you review the other issues as listed below.

2. System Lock Up:

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC® 9800OEC® FluoroTrak 9800 PlusOEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System

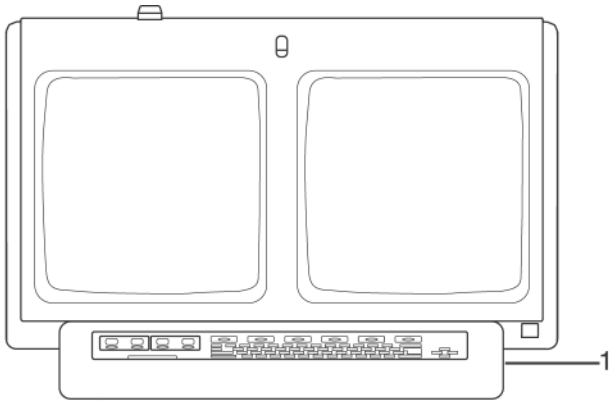
GEHC OEC has become aware of a potential problem with the above-indicated products where the C-arm may lock-up. Specifically, during system usage, the system may fail to function (produce live x-rays), and the collimators may close. In addition, the system display may indicate that the system is active (such as sound and/or light displays) when, in fact, the system is not producing live x-rays. The left monitor of the system will not update (no live fluoroscopy). There will be no radiation emission occurring despite the audible and visual indicators. If it is suspected that the system has emitted an uncommanded radiation exposure the user should contact GEHC to have the exposure logs reviewed to confirm if an exposure was made.

In critical clinical scenarios in which the C-arm is being used to make real-time therapeutic decisions or guide real-time interventions, a system lock-up may cause a procedural delay. Users should always be certain that the images shown on the Left Monitor are refreshing and are in fact live x-ray images (one indicator of this status is that the word "live" displayed on the screen).

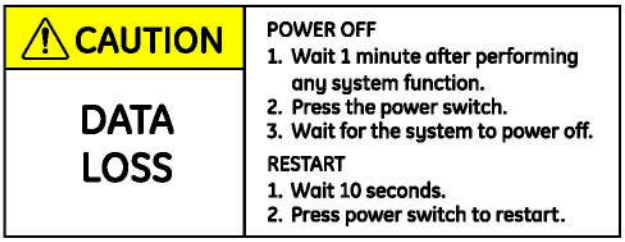
Interim Solution:

Should your OEC System experience a Lock-up, restarting (rebooting) the system should restore system functionality. The restarting (reboot) procedure for OEC 9800 Plus, OEC Flexiview 8800, and OEC UroView 2800 will take less than 3 minutes. **Images saved prior to the system locking up will be restored and are retrievable. Images not saved prior to the system failure will not be restored.** At this time a corrective solution for the OEC 9800 Plus, OEC Flexiview 8800, and OEC UroView 2800 is under investigation. Your facility will be notified as soon as a solution has been identified.

Instructions for rebooting (restarting) the system are located in the Operators Guide. **In addition enclosed is a sheet of supplemental stickers, including instruction for attachment, which demonstrates the restart steps. These stickers should be promptly attached to your system(s)as indicated below (suggest placement in location #1).**



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

3. Incorrect Image Display:

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC® 9800OEC® FluoroTrak 9800 PlusOEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, OEC® Miniview 6800

When the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system. The actual images, however, are labeled with the correct patient information, and may be located within another patient's file.

Interim Solution:

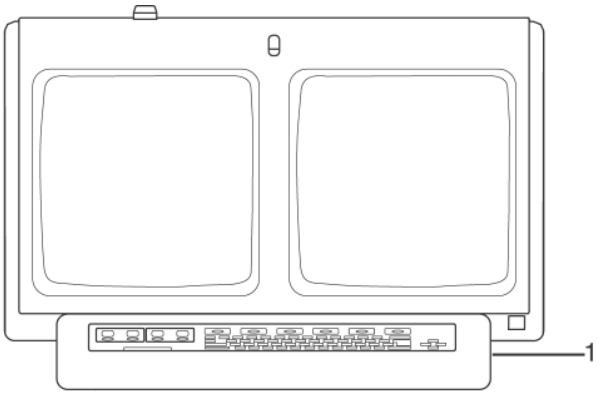
At this time a corrective software solution for the OEC 9800 Plus, OEC FlexiView 8800, OEC UroView 2800, and OEC MiniView 6800 is under investigation. Your facility will be notified as soon as a solution has been identified.

To reduce the occurrence of this issue users should follow the correct power down procedure.

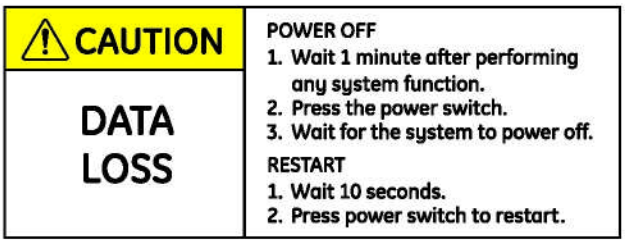
The power down procedure is also described in the Operators Guide and on the supplemental stickers enclosed with this notification.

The supplemental stickers should be installed on your system(s) promptly following the enclosed instructions and as indicated below (suggest placement in location #1).

Users are advised to exercise caution in using the system by verifying that the image displayed is consistent with current examination being reviewed and contains the correct patient demographic information on the image itself until a comprehensive and permanent solution has been developed.



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

4. Incorrect Dose Area Product/Calculated Air Kerma in "Film Mode " and "Digital Spot Mode":

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC®, 9800OEC® FluoroTrak, 9800 PlusOEC®, 9800 Plus, OEC® 9800*MD* Motorized C-arm System

An issue has been reported that results in incorrect calculation, display and recording of patient dose while in film or digital spot mode. During a procedure, both the calculated Cumulative Air Kerma and the Air Kerma Rate can be observed on the live imaging monitor. This shows the AKR (air kerma rate) during fluoro exposures, and CAK (cumulative air kerma) after & between

fluoro acquisitions. Either during the procedure, or more typically, after the procedure, Cumulative Air Kerma and/or Dose Area Product (DAP is optional, depending on system configuration) can be viewed in a Dose Summary Screen, which can be invoked and displayed on the left monitor. This summary shows the total procedure CAK and DAP with a breakdown on what exposure modes were used, and what fractions of the total dose each mode was responsible for. In GE OEC systems, AKR is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK is calculated from the same, but accumulated over the duration of the procedure. DAP is calculated from the same parameters and also the collimator opening area. The total dose listed on this screen will be incorrect only if the Film or Digital Spot are used during the relevant procedure. All other fluoroscopic modes correctly display the dose within current specifications (i.e. Fluoro, High Level Fluoro, Pulsed, Cine Record). This mis calculation could lead the clinicians to erroneously document the radiation exposure received by the patient

Interim Solution:

At this time a corrective solution for the FlexiView 8800 Mobile C-Arm, OEC® UroView 2800 OEC®, 9800OEC® FluoroTrak, 9800 PlusOEC®, 9800 Plus, OEC® 9800MD Motorized C-arm System is under investigation. Your facility will be notified as soon as a solution has been identified. In clinical scenarios in which an accurate record of the radiation exposure to the patient is required prior to the system receiving an upgrade, users should contact their GEHC OEC service provider for assistance in determining the actual radiation exposure.

5. System does not boot:

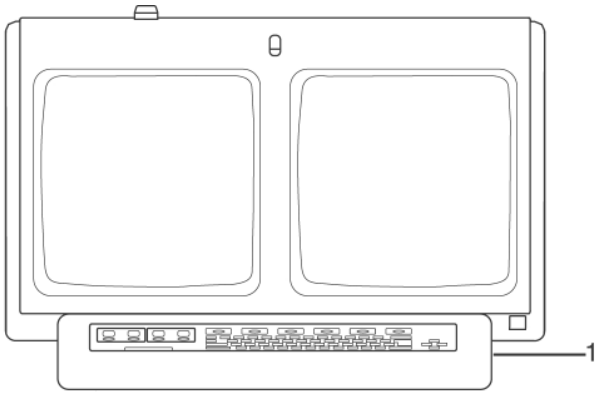
Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, and OEC® Miniview 6800

FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, and OEC® Miniview 6800 may stall during its boot cycle causing a delay in usage. If this condition persists for longer than a minute, the system is stalled.

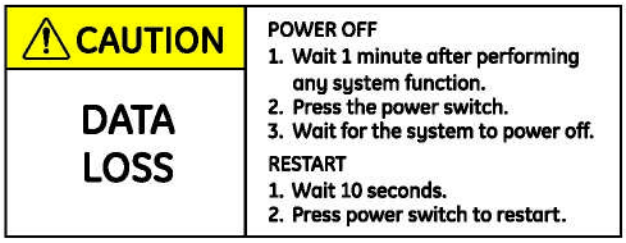
Interim Solution:

Rebooting the system should clear the issue and restore system functionality. When rebooting the system for this issue, before reapplying power, it is important to place the power switch in the OFF position and wait **10 seconds**. Should the system fail to reboot a second attempt at rebooting may be required. These instructions are located in the Operators Guide.

In addition enclosed is a sheet of supplemental stickers, including instructions for attachment that demonstrates the restart steps. These stickers should be promptly attached to your system(s) as indicated below (suggest placement in location #1).



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

GEHC OEC is actively working on solutions that will permanently resolve each of these issues. When solutions become available for those issues that currently do not have a permanent solution, GEHC OEC will contact you and without charge, remedy these issues. For those issues that currently have a permanent fix identified, the GEHC OEC service team will be contacting you to install the correction shortly.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@med.ge.com

Certified Mail Return Receipt Requested

Important Electronic Product Radiation Warning

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

April 2, 2007

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**OEC® 9900 Elite** **OEC® 9800** **OEC® 8800** **OEC® 6800** **OEC® 2800**

Our records indicate that your facility has one or more of the products listed above.

GE Healthcare has identified an issue affecting the OEC® 9900 Elite, OEC® 9800, OEC® 8800, OEC® 6800, OEC® 2800.

A configuration issue has been discovered that results in the failure of the above listed systems to display the US Standard quantity air kerma as required to describe the radiation output for systems manufactured after June 10, 2006 by 21 CFR 1020.32(k).

For the 9800, 8800, 6800 and 2800 products the Air Kerma and DAP can both be displayed at the same time if properly configured. If not configured correctly, these products will only show the DAP calculation. The 9900 product can only display one value or the other. When the 9900 system is incorrectly configured Air Kerma is not displayed, however, the DAP is.

This issue does not affect the safe operation of your system, however, it does result in your system not being in compliance with 21 CFR 1020.32(k).

Your GEHC OEC service representative will be contacting you in the near future to arrange for an inspection to determine if the issue affects your system and will correct the configuration settings if needed at that time at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO